UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,140	09/28/2006	Dominique Michel	LP-2019	5645

217 7590 05/13/2010

FISHER, CHRISTEN & SABOL
P.O. Box 18385
WASHINGTON, DC 20036

EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1625	
MAIL DATE	DELIVERY MODE
05/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,140	MICHEL ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-14 and 19* is/are rejected.

7)☒ Claim(s) *2-7,15-18,20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action supersedes the previous communication.

Claims 1-20, are pending in this application.

Claims 8-10 are drawn to non-elected inventions.

Restriction Requirement

The election of group I, claims 1-7, 11-15, with traverse in the Paper filed 6/1/09, is hereby acknowledged. However, no reason is given for the traversal. Therefore, the restriction is deemed proper and made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11-14, 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaraba et al., Chem. Pharm. Bull., Vol 43(5), (1995), pages 748-753, in view of Staszak et al., EP 0 457 559 A2; Okeda et al., EP 0 955 303 A2, and Antognazza et al., US 5,907,045; individually.

Applicant claims a process of making carboxylic acid salt of compounds of formulae Ia and/or Ib comprising asymmetric hydrogenation a carboxylic acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a disphosphine ligand.

Determination of the scope and content of the prior art (MPEP 2141.01)

Sakaraba et al., teach a process of making HCl acid salt of compounds of formulae Ia and/or Ib comprising asymmetric hydrogenation of an HCl acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a disphosphine

ligand. See reaction schemes in Tables 1-2, pages 748-749. Also, in claims 11, 13-14, applicant claims specific ligands.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of the prior art is that applicant use a salt of carboxylic acid instead of a salt of HCl to prepare the corresponding salt of compounds of formula I. Also, the ligands in claims 11, 13-14 are different from the ligand of the prior art.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, Staszak et al., teach similar process using HCl salts with aminoketones, wherein R1 is thienyl ring. The prior art also teach that salts of other acids such as carboxylic acids (e.g. oxalate) are applicable. See page 5, lines 2-7. Okeda et al., (pages 1-24, particularly, page 2, lines 11-15) and Antognazza et al., (col. 1-8) teach the ligands in claims 11, 13-14, are useful for asymmetric hydrogenations reactions. Using catalytic amount of the catalyst is inherent in claim 1. Therefore, it is not a limitation since the amount is not specific with support in the specification.

Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art of asymmetric hydrogenation of aminoketones would have known to use a salt of carboxylic acid and/or change the ligand in the process by Sakaraba et al., at the time this invention was made. The motivation is from the teachings of Staszak et al., that salts of carboxylic acids are applicable and from the various ligands disclosed by Okeda et al., and Antognazza et al.

According to the court in *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.,* Appeal Nos. 83-513, 83-525 Slip op. at 13 (Fed.Cir. May 16, 1983, 217 USPQ 1281, 1281). Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems

encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. The court went further that:

> Although educational level of inventor may be [a] factor to consider in determining level of ordinary skill in art, it is not conclusive; other factors that may be relevant in ascertaining level of ordinary skill in art include various prior art approaches employed, types of problems encountered in art, rapidity with which innovations are made, sophistication of technology involved, and educational background of those actively working in field.

The court in Environmental Designs, Ltd. et. al. v. Union Oil Company of California et al., 218 USPQ 865 (Fed. Cir. 1983), states

> Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. The important consideration lies in the need to adhere to the statute, i.e., to hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art" -- not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand.

At the time the instant invention was made, workers are engaged in asymmetric hydrogenation of an HCl acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a disphosphine ligand. It was not known if there was problem with salts of HCl acid but, other workers such as Staszak et al., suggest a salt of carboxylic acid is applicable. Okeda et al., and Antognazza et al., teach various catalysts comprising a transition metal complex of a disphosphine ligand.

Therefore, it would have been obvious to try a salt of carboxylic acid or change the ligand in the process of Sakaraba et al., by any worker engaged in asymmetric hydrogenation of an HCl acid salt with aminoketones of formula II, including the inventor,

at the time the invention was made. The choice of a salt of carboxylic acid or ligand represents a finite and predictable solution. It has a reasonable expectation of success because Staszak et al., Okeda et al., and Antognazza et al., made such predictions.

Alternatively, applicant has substitute one known element (a salt of carboxylic acid/ligand) for another (a salt of HCl acid/ligand) to obtain a result predicted by Staszak et al., Okeda et al., and Antognazza et al. The instant invention is a modification of the process by Sakaraba et al., grounded in common sense because Staszak et al., Okeda et al., and Antognazza et al., suggested it could be done. "When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *United States v. Adams,* 383 U.S. 49, 50-51 (1966). Cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR, supra.*

Alternatively, the instantly claimed process of using carboxylic acid salts and ligands in asymmetric hydrogenations is not applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done nothing more than combine separate but well-known "prior art[s'] inventions from Sakaraba et al., and Staszak et al., according to known methods to yield predictable results. Applicant's result is predicted by the prior arts.

While the combination may perform a useful function it did no more than what they would have done separately. In re Anderson, 396 U.S. 57, 163 USPQ 673 (1969) cited in KSR Int. Co. v. Teleflex Inc, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields

predictable result, the combination is obvious. In re Sakraida, 425 US 273, 189 USPQ 449 (1976) cited in KSR, supra. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 187 USPQ 303 (1950), cited in KSR, supra.

Response

Applicant's arguments filed 2/2/10 have been fully considered but they are not persuasive. Applicant contends the Office action fails to resolve the level of ordinary skill in the art. This is not persuasive because applicant's argument is a conclusive statement, not supported with evidence, legal and or factual analysis of who is an ordinary skill in the art and how such analysis relates to applicant's position.

Objection

Claims 2-7, 15-18, 20, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

May 8, 2010